

VHCURES DUA Application Review Form

VHCURES DUA Applicant Agency/Organization: RTI International

Applicant Type (State Agency or Non-State Entity): Non-State Entity: Non-profit research organization

Date DUA Application Received by GMCB Staff: 5/3/2018

GMCB Application Reviewer: Dian Kahn

Project Title: Treatment and Outcomes for Patients with Opioid Use Disorder (OUD) after Cessation of Opioid Prescriptions

Application Summary: The VHCURES data is needed to support analyses of utilization patterns of de-identified individuals who are misusing/abusing prescription opioids and then are no longer filling opioid prescriptions to explore the following research questions:

1. What factors are associated with OUD treatment initiation for patients who exhibit patterns of abusive fills of prescription opioids after physicians stop refilling their prescriptions?
2. What factors are associated with longer engagement in OUD treatment for patients who initiate treatment?

The first aspect of this study examines potential barriers to OUD treatment initiation, while the second aspect examines potential barriers to treatment engagement among individuals who do initiate treatment. The analysis will be conducted for individuals with Medicaid and private insurance because treatment patterns, the availability of services, and barriers to care may differ for those two insurance populations.

GMCB Reviewer Summary of Findings for DUA Application: RTI International filed a complete and detailed pre-application screening assessment and a DUA application that demonstrate intent to utilize the VHCURES dataset in a manner that complies with the requirements of a VHCURES data use agreement (DUA) and also potentially contributes to the body of knowledge that would serve the public interest by addressing the opioid addiction crisis in Vermont and at a national level. This study intends to address the challenge of low engagement rates in treatment in Vermont and nationally and factors that could improve retention that would be of interest to State of Vermont providers, payers, and stakeholders, as well as federal agencies such as SAMHSA, HRSA, CMS, ONDCP, and NIH. The study is internally funded by RTI International. The applicant has no intention to redisclose to subcontractors or to link the VHCURES data with other external data sources that could directly or indirectly re-identify individuals in the VHCURES limited use data set.

GMCB Reviewer Recommendation on Application: RTI's DUA application proposes to use commercial insurance and Medicaid eligibility and claims data in a manner that supports the research purpose. The proposed study addresses challenges of the opioid addiction crisis in Vermont and on a national level. RTI will not be linking the VHCURES data with any other external data sources and its described policies and procedures for data security and protection are well documented and meet standards for PHI. The intended uses of the data meets the GMCB's statutory charge for uses of the claims data and make this

an application that the GMCB is likely to approve. DVHA approved the proposed use of Medicaid data on 5/15/18.

Summary of Review Process and Timeline:

<p style="text-align: center;">DVHA Decision on Request for Disclosure and Use of Medicaid Data</p> <p>Date GMCB Reviewer Circulated the Application Decision Form to DVHA: 5/15/2018</p> <p>DVHA Recipient of Application Decision Form: Darcy Putzier on behalf of Cory Gustafson</p> <p>DVHA Signatory to the Application Decision Form: Cory Gustafson, Commissioner</p> <p>Date DVHA Request Form Signed: 5/15/2018</p> <p>DVHA Response to the Application Decision Form:</p> <p>(X) Approved () Denied () Other response:</p> <p>Summary of Action Taken by Reviewer Following the DVHA Decision:</p>

GMCB DUA Application Decision Maker: Susan Barrett, Executive Director

Date the Reviewer Circulated the Application/ Review Form to GMCB Staff for Review:

Date of GMCB Decision Maker Review and Decision:

Decision Maker Response to the Application:

- () Approved
- () Denied
- () Other response:

GMCB Decision Maker Signature Section

Name (Print):

Signature:

Title:

Date of Signature:

Summary of Action Taken by Reviewer Following Decision Maker Response:

DUA Application Header Information

State Agency Name	Not applicable
Non-state Entity Name	RTI International
Application File Name	RTI 2018_2 Opioid_Application
Date Application Filed with GMCB	5/3/2018
Date Application Deemed Complete	5/3/2018
Authorized User Signatory	Tony Dawson, Supply Chain Specialist
Principal Investigator 1	Susan Haber, Director, Program on Health Coverage for Low-Income and Uninsured Populations
Principal Investigator 2	Not applicable
Principal Investigator 3	Not applicable
Data Custodian 1	Jennifer Popovic, Data Custodian
Data Custodian 2	Not applicable
Data Custodian 3	Not applicable
Project Title	Treatment and Outcomes for Patients with Opioid Use Disorder (OUD) after Cessation of Opioid Prescriptions
Data Lines of Business Requested	Commercial Insurance, Medicaid
Date Application Sent to DVHA	5/15/2018
Date Application Approved by DVHA	5/15/2018
Date Application Denied by DVHA	Not applicable
External Agent 1 Immediate Data Rediscovery	Not applicable
External Agent 2 Immediate Data Rediscovery	Not applicable
External Agent 3 Immediate Data Rediscovery	Not applicable
Date Data Rediscovery Request Filed: Agent 1	Not applicable
Date Data Rediscovery Request Filed: Agent 2	Not applicable
Date Data Rediscovery Request Filed: Agent 3	Not applicable

Key Requirements Checklist

Attachments, Sections, Subsections	Description	Status
Attachment 2	Data Governance Policies & Procedures	Complete
Attachment 3 (State Agencies)	Copies of proposed or signed contracts, agreements with external agents	Not applicable
Attachment 3 (Non-state Entities)	Limited Use Research File Specification	Complete

Attachment 4 (State Agencies)	Data Rediscovery Request Form(s) for External Agents	Not applicable
Attachment 4 (Non-state Entities)	Copies of proposed or signed contracts, agreements with external agents	Not applicable
Attachment 5 (State Agencies)	Data Governance Policies & Procedures for External Agents	Not applicable
Attachment 5 (Non-state Entities)	Copies of proposed or signed contracts, agreements with external agents	Not applicable
Attachment 6 (If applicable)	Institutional Review Board Approval Documents	Filed Exempt Determination for IRB review
Attachment 6 (Non-state Entities)	Data Governance Policies & Procedures for External Agents	Complete
Attachment 7 (State Agencies)	Other materials requested by GMCB	Not applicable
Attachment 7 (Non-state Entities)	Institutional Review Board Approval Documents	Filed Exempt Determination for IRB review
Attachment 8 (Non-state Entities)	Other materials requested by GMCB	Not applicable
1: 1-2	Authorized User acknowledges agreement with check marks	Complete
1: 1-3, items 1 & 2 (Yes, Medicare data)	Project directed and funded by State	No
1: 1-4: Non-state Entities	Files Requested excludes Medicare	Yes
1: 1-5-5: Proposed linking with other data sources	Lists and describes other record-level data sources, methodology, PHI protection measures	No
2: 2-2-2: Requests encrypted hard media	Full explanation of reasons that SFTP transmission of data is not an option	No
3: 3-1, 3-2, 3-3	Complete contact information for AU, PI(s), DC(s)	Yes
3: 3-4	List of Individual Users for initial DUA	Yes
5	Complete information for primary contact for data transmission logistics	Yes
6	Signatures: AU, PI(s)	Yes

Section 1: Research Summary

1-1 Research Summary

(X) YES () NO AU Signatory has authority to bind agency/organization to legal agreements.

(X) YES () NO Project Name and Description in alignment with item 1-5-1.

YES NO NA Funding sources include State for State Agency requesting Medicare data.

YES NO NA If Non-state Entity, intended research purpose (item 1-5-1) justifies use of requested lines of business data subsets.

YES NO NA Identified external agent if filing Attachments 3, 4, 5 with the application.

1-2 Authorized User Acknowledgements

YES NO See Key Requirement Checklist above.

1-3 Project Questions

YES NO NA If State Agency (including external agent) requesting Medicare data subset, "Yes" project is directed AND partially or wholly funded by the State of Vermont.

YES NO NA If **YES** to direct generation of revenues and income from the project, explanation from the applicant and reviewer opinion:

YES NO Project meets at least one of the statutory criterion (public health activity excluded) for uses of the GMCB data resources in the unified health care database.

YES NO NA Project includes proposed linking of VHCURES with other data sets, details included under item **1-5-5**.

YES NO NA Project anticipates need for immediate re-disclosure of data to external agent(s), attachments 3, 4, 5 have been filed with the application.

1-4 Requested Data

YES NO NA If Non-state Entity, intended research purpose (item 1-5-1) justifies use of requested lines of business data subsets.

YES NO NA If Non-state Entity is a federal contractor requesting access to Medicare data, CMS has granted approval to GMCB to release the VHCURES Medicare data subset to this entity to support federal research project.

YES NO NA If Non-state Entity, the Data Years or Date Range align with the intended research purpose (item 1-5-1).

YES NO NA If State Agency has not included all three data subsets in the request, GMCB has confirmed with the requestor that a new DUA application may be required to expand the request to all three subsets.

1-5 Project Overview

1-5-1 YES NO Does the application adequately describe how the proposed research will contribute to generalizable knowledge applicable to the Vermont population, health, health care and to the State of Vermont's programs?

Reviewer comments **if major concerns** about the project:

1-5-2 YES NO NA If the request includes Medicaid data, does it propose use of the data to support public health activities?

Reviewer comments:

1-5-3 YES NO Are credentials, skills, and experience adequate to support the research purpose?

Reviewer comments: Highly experienced and credentialed research team with expertise in quantitative analyses and policy studies addressing health care delivery systems, substance abuse treatment, and interaction with population characteristics.

1-5-4 YES NO Applicant understands and adequately addressed principle of "minimum necessary data."

Reviewer comments:

1-5-5 YES NO NA Applicant provided adequate detail for 1-3 Project Question indicating intent to link data.

Reviewer comments **if concerns** about the proposed data linking:

1-5-6 YES NO Any concerns about funding sources?

Reviewer comments **if concerns** about the funding source(s):

1-5-7 YES NO NA Was the IRB for the project attached to the application if applicable?

Reviewer comments: RTI filed an IRB Exemption form per RTI protocol for reviewing proposed research projects.

Section 2: Data Management Plan

2-1 Physical Possession and Storage of Data Files

(X) YES () NO Did the applicant file the organization's published policies and procedure for data governance and protection as Attachment 2 to the application?

If Attachment 2 was **not filed** with the application or does not adequately address the topic, explain:

Do the applicant's responses and the organization's published policies and procedures for data governance and protection if filed, **satisfactorily address** the following?

2-1-1 (X) YES () NO Tracking data users and locations of the original data file and any derived files with record level, claim line level data that may be accessed on local storage devices and from external storage and network systems.

Reviewers comments **if concerns**:

2-1-2 (X) YES () NO Monitoring compliance of all members of the research team with the organization's privacy and data protection policies and procedures and as required by the VHCURES DUA.

Reviewers comments **if concerns**:

2-1-3 (X) YES () NO Implementing procedures to tracking the status and roles of members of the research team including notification of the GMCB about staffing changes (filing new user affidavits).

Reviewers comments **if concerns**:

2-1-4 (X) YES () NO Training and educating staff on protection of sensitive data such as protected health information.

Reviewers comments **if concerns**:

2-1-5 (X) YES () NO Describing protocols for suspected or actual data breaches.

Reviewers comments **if concerns**:

2-1-6 (X) YES () NO Describes actions to be taken to physically secure the files in motion, on services, and hard media.

Reviewers comments **if concerns**:

2-1-7 () YES (X) NO Will data be transmitted, stored or transferred outside of the continental United States?

If YES, reviewer comments:

2-2 Data Sharing, Electronic Transmission, Distribution

2-2-1 (X) YES () NO Does the applicant satisfactorily address policies and procedures for sharing, transmitting, and distributing the data set and derived files?

If NO, reviewer comments:

2-2-2 () YES (X) NO Does the applicant anticipate requesting to receive the data set via encrypted hard media?

If YES, reviewer comments:

2-2-3 () YES (X) NO () Maybe Does the applicant have an interest in accessing the data set via an enclave option in the future?

If NO, reviewer comments: Concerned about fees and prefer to receive the data via SFTP and then manage the data using RTI's policies, procedures, and infrastructure to support it.

2-2-4 (X) YES () NO Does the applicant (and external agent as applicable) satisfactorily address methods for tracking, monitoring, and auditing access to and use of data?

If NO, reviewer comments:

2-2-5 (X) YES () NO Does the applicant (and external agent as applicable) satisfactorily address policies and procedures for defining data access privileges by roles including PI, DC, analysts and researchers, administrative support, IT support, etc.?

If NO, reviewer comments:

2-2-6 () YES () NO Does the applicant (and external agent as applicable) satisfactorily address technical safeguards for data access?

If NO, reviewer comments:

2-2-7 () YES () NO () NA Does the reviewer have any concerns about how the applicant's external agents will access and manage the data?

If YES, reviewer comments:

2-2-8 () YES () NO () NA If additional copies of the data will be housed in separate locations, does the reviewer have any concerns about how the data will be transferred?

If YES, reviewer comments:

2-3 Data Reporting and Publication

2-3-1 () YES () NO Does the applicant satisfactorily address processes for reviewing publications prior to public release in a manner that demonstrates an understanding of the VHCURES DUA requirements addressing public reporting?

If NO, reviewer comments:

2-4 Completion of Research Tasks and Data Destruction

2-4-1 () YES () NO Does the applicant demonstrate an understanding of the requirements for final data destruction and filing of a certificate of destruction?

If NO, reviewer comments:

2-4-2 () YES () NO Does the applicant (and external agent as applicable) satisfactorily address policies and procedures for individual data users at the termination of their participation in the project that supports data protection?

If NO, reviewer comments:

2-4-3 (X) YES () NO Does the applicant (and external agent as applicable) satisfactorily address policies and procedures to ensure discontinuation of use of the data set and derived data files following completion of the project?

If NO, reviewer comments:

Section 3: Project Team

3-1 (X) YES () NO Did applicant provide complete contact information for the Authorized User?

If NO, reviewer comments:

3-2 (X) YES () NO Did applicant provide complete contact information for the Principal Investigator(s)?

If NO, reviewer comments:

3-3 (X) YES () NO () NA Did applicant provide complete contact information for the Data Custodian(s)?

If NO, reviewer comments:

3-4 (X) YES () NO Does the inventory of Individual Data Users align with the information filed with the DUA application in terms of identifying project participants both within the AU's organization and as applicable, the external agent's organizations?

If NO, reviewer comments:

(X) YES () NO Does the application include Project or Role Titles for all individual users listed in the table?

If NO, reviewer comments:

Section 5: Data Transmission and Receipt

(X) YES () NO () NA (Not applicable if AU is planning to exclusively access the data via the enclave)

Did the applicant provide complete contact information for the Data Transmission Logistics?

If NO or any concerns, reviewer comments:

Section 6: Signatures

(X) YES () NO Authorized User signature and date completed?

(X) YES () NO Principal Investigator(s) signature(s) and date(s) completed?

If any concerns, reviewer comments: